

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

IN RE: SUBOXONE (BUPRENORPHINE
HYDROCHLORIDE AND NALOXONE)
ANTITRUST LITIGATION

MDL No. 2445

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This Document Relates to:

All End-Payor Actions

**MEMORANDUM OF LAW IN SUPPORT OF
END-PAYOR PLAINTIFFS' MOTION FOR CLASS CERTIFICATION**

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I. INTRODUCTION

This antitrust class action is brought by consumers and third-party payors (collectively “End-Payers” or “EPPs”) who purchased, paid, and/or reimbursed for co-formulated buprenorphine hydrochloride and naloxone hydrochloride dehydrate (“Suboxone”). Plaintiffs allege that they would have paid significantly less for Suboxone but for the anticompetitive conduct of Suboxone’s manufacturer: Indivior Inc., f/k/a Reckitt Benckiser Pharmaceuticals, Inc. (“Defendant” or “Reckitt”).

EPPs—the last purchasers in the Suboxone distribution chain—request certification of a nationwide injunctive class under Fed. R. Civ. P. 23(b)(2) and an issues class under Fed. R. Civ. P. 23(c)(4). Mindful of this Court’s analysis in the *Provigil* litigation,¹ EPPs seek the efficiencies that class-wide adjudication of liability issues will bring, but *do not* seek class treatment for the antitrust injury and damages elements—elements that gave rise to the Court’s reasoning in *Provigil*.² By certifying an EPP class on the issue of unlawful conduct—but not class-wide antitrust injury and aggregate damages—this Court will ensure that the claims of Direct Purchasers, EPPs, and States can be tried together on liability,³ before one jury. If Plaintiffs prevail in that trial, individual EPP class members can then proceed with follow-on proceedings in their respective jurisdictions to determine individual antitrust impact and damages. A trial of the issues common to the EPP class and the other plaintiff groups will greatly simplify and streamline the EPPs’ ultimate pursuit of full redress.

¹ *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1833, ECF No. 438 (E.D. Pa. June 10, 2015); ECF No. 456 (E.D. Pa. Aug. 4, 2015).

² End-Payor Plaintiffs respectfully maintain that all of the elements of Rules 23(a) and (b)(3) can be satisfied and are supported by the record here. In light of the *Provigil* decision, however, EPPs believe that seeking certification of an issues class is in the best interest of the class as a whole.

³ Satisfaction of the elements presented for certification below will satisfy liability under all of EPPs’ state laws. *See infra*, Section IV.D.

II. STATEMENT OF FACTS

EPPs pay for Suboxone for their own use, or that of their members, and since they do not resell Suboxone, EPPs do not pass on any amount of the overcharges they pay. The proposed EPP Classes consist of consumers and health plans covering millions of lives and are represented by seven health plans that provide prescription drug coverage for their members. Absent Reckitt's misconduct, Plaintiffs would have paid far less for Suboxone than they did.

Plaintiffs allege that Reckitt engaged in an intricate anticompetitive scheme to maintain and extend its monopoly power in the Suboxone market. Reckitt knew that once its regulatory exclusivity period for brand-name Suboxone tablets ended on October 8, 2009, it would experience a drastic loss of sales because less expensive generic Suboxone tablets would enter the market at a lower price.⁴ To stave off this competition and the resultant loss of profits, Reckitt executed a multi-step scheme to keep prices artificially high.

First, Reckitt implemented a "product hop" from the endangered tablet to its patented sublingual Suboxone film. The goal was to obliterate the market for incoming generic Suboxone tablets. Reckitt knew that, as a matter of state generic substitution law and through the systematic functioning of managed care, the overwhelming majority of existing Suboxone tablet prescriptions would be automatically substituted with less expensive generic versions. To combat this, Reckitt introduced the Suboxone film product on August 30, 2010 before any generic tablets were approved.⁵ Suboxone film, unlike the tablet, enjoys patent protection until 2023 and therefore does not face imminent generic competition. To take advantage of this, once the FDA approved Suboxone film, Reckitt used its sales force aggressively to destroy demand for the

⁴ End Payor Pltfs' Second Consol. Amended Class Action Compl., Apr. 13, 2015, ECF No. 149 ("Complaint" or "Compl.") at ¶¶ 8-9.

⁵ *Id.* at ¶ 16.

tablet and switch prescriptions to its patented film product by making unfounded claims that tablets were unsafe and artificially raising their tablet price relative to film.⁶ As a result, once generic Suboxone tablets launched in February 2013, the market for tablets had been virtually eliminated by Reckitt's product hop to the film.⁷ When Reckitt stopped selling the tablets altogether less than a month later, the market for tablets essentially vanished.

In the lead-up to these events, Reckitt had engaged in activities intended to thwart generic competition long enough to enable the "product hop" to occur. For example, it delayed FDA approval of Abbreviated New Drug Applications ("ANDAs") for generic Suboxone tablets by purposefully frustrating the development of an FDA-mandated risk management plan. On January 6, 2012, the FDA had informed Reckitt and generic manufacturers of the need to submit a joint Risk Evaluation and Mitigation Strategy ("REMS") to ensure that the benefits of Suboxone tablets outweighed its risks.⁸ Knowing that the REMS was the final prerequisite for ANDA approval, Reckitt sabotaged the joint process, thus delaying FDA approval of at least one ANDA and delaying generic competition for Suboxone tablets in the process.⁹

Reckitt also filed a sham Citizen's Petition with the FDA to further delay approval of generic Suboxone tablets. On September 25, 2012, with approval of at least one ANDA imminent, Reckitt filed a Citizen's Petition alleging that a safety issue was forcing it to remove its tablet product from the market.¹⁰ This delayed the FDA's approval of the Suboxone tablet ANDA until February 22, 2013 – the same day the FDA denied Reckitt's Citizen's Petition.¹¹

⁶ *Id.* at ¶¶ 42-45.

⁷ *Id.* at ¶ 46.

⁸ *Id.* at ¶ 50.

⁹ *Id.* at ¶¶ 52-59.

¹⁰ *Id.* at ¶ 70.

¹¹ *Id.* at ¶¶ 71, 80.

By this time, Reckitt had successfully converted the vast majority of Suboxone tablet sales to its film product.¹²

Plaintiffs seek certification of a class for injunctive relief applicable to a nationwide class of consumers and Third-Party Payors (“TPPs”) affected by Reckitt’s conduct. Plaintiffs also seek class certification of End-Payors in eleven states on all elements of Defendant’s alleged unlawful conduct *except* antitrust impact and damages. The facts and evidence proving Defendant’s unlawful conduct – including “product hopping” to Suboxone film and hindering ANDA approvals via manipulation of the REMS process and a sham Citizen’s Petition – are common to the class. Plaintiffs’ claims are ideally suited for class treatment because they arise exclusively from Reckitt’s anticompetitive scheme to impede generic entry and all elements of Reckitt’s conduct will be proven with common class-wide evidence.

III. LEGAL STANDARD

Antitrust cases are especially well-suited for class treatment.¹³ Plaintiffs bear the burden of affirmatively demonstrating compliance with Rule 23 by a preponderance of the evidence. *Byrd v. Aaron’s Inc.*, 784 F.3d 154, 163 (3d Cir. 2015). Plaintiffs must establish that they meet each of the four requirements in Rule 23(a): (1) the Class is so numerous that joinder of all members is impracticable (“numerosity”); (2) there are questions of law or fact common to the Class (“commonality”); (3) the claims or defenses of the representative parties are typical of the claims or defenses of the Class (“typicality”); and (4) the representative parties will fairly and

¹² *Id.* at ¶¶ 46, 71.

¹³ *See, e.g., Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S. Ct. 736, 739 (2014) (noting that “class action lawsuits are an important and valuable part of the legal system”); *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (“Predominance is a test readily met in certain cases alleging . . . violations of the antitrust laws.”); *In re Rubber Chems. Antitrust Litig.*, 232 F.R.D. 346, 350 (N.D. Cal. 2005) (“Class actions play an important role in the private enforcement of antitrust actions.”).

adequately protect the interests of the Class (“adequacy of representation”). *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 309 n.6 (3d Cir. 2008).

If all four requirements of Rule 23(a) are met, then plaintiffs must satisfy at least one of the requirements of Rule 23(b) if they seek a Rule 23(b)(1), (b)(2), or (b)(3) class. *Id.* A Rule 23(b)(2) class may be maintained where “the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole[.]” FED. R. CIV. P. 23(b)(2).

As an alternative to the Rule 23(b) class option, “plaintiffs may resort to Rule 23(c)(4) to isolate the common issues and proceed with class treatment of these particular issues.” *Cave v. Saxon Mortgage Servs., Inc., Nos. 11-4586, 12-5366*, 2016 WL 5930846, at *3 (E.D. Pa. Oct. 11, 2016) (citations omitted). Rule 23(c)(4) states that “[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues.” Under this rule, a court may grant class certification for litigation of certain issues, while allowing the remaining ones to proceed on an individual basis. *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 272 (3d Cir. 2011). “The ability to certify issue classes accords the courts discretion to realize the advantages and efficiencies of class-wide adjudication of common issues when there also exist individual issues that must be tried separate.” *Cave*, 2016 WL 5930846, at *3 (citing Newberg on Class Actions, § 4:89 (5th ed. 2012)); *see also In re Chiang*, 385 F.3d 256, 267 (3d Cir. 2004) (“[C]ourts commonly use Rule 23(c)(4) to certify some elements of liability for class determination, while leaving other elements to individual adjudication—or, perhaps more realistically, settlement.”); *Carnegie v. Household Int’l, Inc.*, 376 F.3d 656, 661 (7th Cir. 2004) (“It may be that if and when the defendants are determined to have violated the law separate proceedings of some character will be required to determine the entitlements of the individual class members to relief.”).

The Third Circuit has held that the decision to certify an issues class under Rule 23(c)(4) is “analytically independent” from Rule 23(b)(3)’s predominance inquiry, and a district court must consider a different set of factors in deciding certification. *Gonzalez v. Corning*, 885 F.3d 186, 202 (3d Cir. 2018). Those factors include:

[T]he type of claim(s) and issue(s) in question; the overall complexity of the case; the efficiencies to be gained by granting partial certification in light of realistic procedural alternatives; the substantive law underlying the claim(s), including any choice-of-law questions it may present and whether the substantive law separates the issue(s) from other issues concerning liability or remedy; the impact partial certification will have on the constitutional and statutory rights of both the class members and the defendant(s); the potential preclusive effect or lack thereof that resolution of the proposed issue class will have; the repercussions certification of an issue(s) class will have on the effectiveness and fairness of resolution of remaining issues, the impact individual proceedings may have upon one another, including whether remedies are indivisible such that granting or not granting relief to any claimant as a practical matter determines the claims of others; and the kind of evidence presented on the issue(s) certified and potentially presented on the remaining issues, including the risk subsequent triers of fact will need to reexamine evidence and findings from resolution of the common issue(s).

Gates, 655 F.3d at 273 (citing Principles of the Law of Aggregate Litigation §§ 2.02-05 (2010); *Hohider v. United Parcel Serv., Inc.*, 574 F.3d 169, 201 (3d Cir. 2009)).¹⁴ This Court is vested with broad discretion to examine the foregoing factors and establish procedures that ensure sound and efficient case management through certification of issues classes.¹⁵

¹⁴ In *Hohider*—the issues class case preceding *Gates*—the Third Circuit noted a split in authority among the Courts of Appeal as to whether Rule 23(b) elements needed to be satisfied in order for plaintiffs to secure a Rule 23(c)(4) issues class, or whether satisfaction of Rule 23(a) elements alone was sufficient; the Court did not answer the question at the time. *Hohider*, 574 F.3d at 200 n.25. However, two years later, the Third Circuit revisited the issue in *Gates* and established a distinct issues class test (enumerated above). *Gates* formally untangled Rule 23(c)(4) issues class analysis from Rule 23(b) analysis while also establishing an issues class test that is more rigorous than satisfaction of the Rule 23(a) elements alone. *Gates*, 655 F.3d at 273 (“Rather than joining either camp in the circuit disagreement, we believe the considerations set forth in *Hohider* and more recently in the Final Draft of the ALI’s Principles of Aggregate Litigation provide the most sound guidance in resolving this complicated area of class action procedure.”).

¹⁵ See, e.g., *Gates*, 655 F.3d at 272 (quoting *Chiang v. Veneman*, 385 F.3d 256, 267 (3d Cir. 2004) (Rule 23(c)(4) gives courts “ample power to treat common things in common and to

IV. ARGUMENT

Plaintiffs have satisfied the requirements of Rule 23(a), as well as the prerequisites for both a Rule 23(b)(2) injunctive class and a Rule 23(c)(4) issues class. This action presents uniform, common questions of fact and law regarding Reckitt's unlawful conduct which inflated the price of brand Suboxone and foreclosed the availability of generic Suboxone tablets.

A. Proposed Classes

Pursuant to Fed. R. Civ. P. 23, End-Payor Plaintiffs seek certification of the following classes:

i. Nationwide Injunctive Class

All persons or entities in the United States who purchased and/or paid for some of all of the purchase price for Co-Formulated Buprenorphine/Naloxone ("Suboxone") in any form for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period January 1, 2012 through the date of class certification.

ii. State Antitrust/Consumer Protection Class

All persons or entities who purchased and/or paid for some of all of the purchase price for Co-Formulated Buprenorphine/Naloxone ("Suboxone") in California, Florida, Iowa, Michigan, Minnesota, Mississippi, Nevada, New York, Pennsylvania, Virginia, and Wisconsin in any form for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries at any time during the period January 1, 2012 through the date of class certification.

On the following issues:

- (a) Whether Defendant engaged in anticompetitive and deceptive conduct;

distinguish the distinguishable"); *Hohider*, 574 F.3d at 200-01 ("[A] Court's decision to exercise its discretion under Rule 23(c)(4), like any other certification determination, must be supported by rigorous analysis."); *In re Ins. Brokerage Antitrust Litig.*, 579 F.3d 241, 271 (3d Cir. 2009) ("district court has considerable discretion" on a motion for class certification); *Serio v. Wachovia Sec., LLC*, No. 06-cv-4681, 2009 WL 900167, at *10 (D.N.J. Apr. 2, 2009).

- (b) Whether Defendant willfully maintained monopoly power through such conduct;
- (c) Whether Defendant had a specific intent to monopolize;
- (d) Whether Defendant had a dangerous probability of achieving monopoly power;
- (e) Whether Defendant has offered a non-pretextual procompetitive justification that could not have been obtained through less restrictive means, and if so;
- (f) Whether the anticompetitive effects of Defendant's conduct outweigh their proffered procompetitive benefits, if any.

The following persons or entities are excluded from both proposed Classes: (1) Pharmacy Benefit Managers; (2) Defendant and their officers, directors, management, employees, subsidiaries, and affiliates; (3) all governmental entities, except for government funded employee benefit plans; (4) all persons or entities who purchased Suboxone for purposes of resale or directly from Defendant or its affiliates; and (5) the judges in this case and any members of their immediate families.

B. The Proposed Classes satisfy Rule 23(a)

All four Rule 23(a) requirements have been met by End-Payors' proposed Classes.

i. Class Members Are So Numerous That Joinder Is Impracticable

Rule 23(a)(1) requires that the class be sufficiently numerous that joinder of all members is "impracticable." FED. R. CIV. P. 23(a)(1). It does not require "that joinder would be impossible, but rather that joinder would be extremely difficult or inconvenient." *Jackson v. SEPTA*, 260 F.R.D. 168, 185-86 (E.D. Pa. 2009) (quoting *Szczubelek v. Cendant Mortgage Corp.*, 215 F.R.D. 107, 116 (D.N.J. 2003)). In determining numerosity, "a court may accept common sense assumptions." *In re Linerboard Antitrust Litig.*, 203 F.R.D. 197, 205 (E.D. Pa. 2001) (citation omitted). Generally, though, if the "potential number of plaintiffs exceeds 40, the [numerosity] prong of Rule 23(a) has been met." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 250 (3d Cir. 2016) (citation omitted).

Courts have routinely determined that classes of end-payors for prescription drugs are sufficiently numerous.¹⁶ Further, the exact number of class members need not be known for class certification to be proper. *Osgood v. Harrah's Entertainment, Inc.*, 202 F.R.D. 115 (D.N.J. 2001). The court in *Terazosin* certified a national litigation class of consumers and third-party payors reasoning, “[O]nce the good faith estimate of the class size reaches the thousands, the joinder impracticability test is satisfied.” *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 685 n.21 (S.D. Fla. 2004). Here given the thousands of overcharged Suboxone purchasers in the proposed Classes, the numerosity challenge is easily met.¹⁷

ii. Plaintiffs Present Common Issues of Law and Fact

The Rule 23(a)(2) commonality provision is also met here. This requires that there be “questions of law or fact common to the members of the class.” FED. R. CIV. P. 23(a)(2). A common question is one that “is capable of class-wide resolution – which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.” *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). Commonality “does not require that all class members share identical claims, and indeed factual differences among the claims of the putative class members do not defeat certification.” *In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 148 F.3d 283, 310 (3d Cir. 1998) (quoting *Neal v. Casey*, 43 F.3d 48, 56 (3d Cir. 1994)). A “single common question is

¹⁶ See, e.g., *Wellbutrin XL*, 282 F.R.D. at 137 (granting certification and finding numerosity requirement “easily met in this case because the plaintiffs seek to certify a class of hundreds of thousands of consumer class members and thousands of TPP class members”); *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 217 (E.D. Pa. 2012) (certifying a class, and noting numerosity “planning satisfied as Indirect Purchasers seek to certify a class of tens of thousands of consumer class members and hundreds of TPP class members”).

¹⁷ See Ex. 3 to Wexler Decl. at 5-17 (Defendant’s document highlighting substantial lists of just some of the third-party payor End-Payor Plaintiff class members; consumers purchasers belonging to third-party payors are even more numerous).

sufficient” to establish commonality. *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 137 (E.D. Pa. 2011) (citation omitted).

Where plaintiffs allege anticompetitive activity, the claims ordinarily involve common questions of law and fact because the claims proceed from a single course of conduct. *See, e.g., In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 528 (3d Cir. 2003); *Wellbutrin XL*, 282 F.R.D. at 137 (“Each class members claims depend on whether or not the defendants unlawfully engaged in anticompetitive behavior Although this action is brought under the law of six different states, roof of the essential elements of these statutes will also require common proof.”).

The commonality requirement of Rule 23(a)(2) is satisfied here. The action presents numerous common issues of law and fact which are encompassed by the specific issues sought for certification here, including: (1) the existence of deceptive and anticompetitive conduct; (2) the presence and willful maintenance of monopoly power; and (3) the absence of cognizable procompetitive justifications. Those common issues will be decided by the fact-finder’s analysis of common evidence bearing on questions such as:

- whether Defendant’s anticompetitive scheme suppressed generic competition to Suboxone;
- whether Defendant had the ability to control prices and exclude competition;
- whether Defendant’s deceptive introduction of Suboxone film and destruction of the prescription base for Suboxone tablets was predatory and anticompetitive;
- whether Defendant fabricated a safety issue regarding Suboxone tablets for the sheer purpose of impairing generic competition;
- whether Defendant’s sabotage of the development process for a shared REMS was anticompetitive;
- whether a reasonable petitioner would have expected the arguments made in Defendant’s Citizen’s Petition to succeed;

- whether Defendant submitted the Citizen’s Petition for the purpose of interfering with competition;

Defendant’s conduct is the common thread that runs through each of these issues.

iii. Plaintiffs’ Claims Are Typical of Those of the Classes

Rule 23(a)(3) requires that “the claims . . . of the representative parties are typical of the claims . . . of the class.” FED. R. CIV. P. 23(a)(3). The typicality factor examines “whether the named plaintiffs’ claims are typical, in common-sense terms, of the class, thus suggesting that the incentives of the plaintiffs are aligned with those of the class.” *Beck v. Maximus, Inc.*, 457 F.3d 291, 295-96 (3d Cir. 2006).

Rule 23(a)(3)’s typicality requirement does not mandate that all of the putative class members share identical claims. *Baby Neal*, 43 F.3d at 56, 63; *Hassine v. Jeffes*, 846 F.2d 169, 176-77 (3d Cir. 1988).¹⁸ As with commonality, “[f]actual differences will not defeat typicality if the named plaintiffs’ claims arise from the same event or course of conduct that gives rise to the claims of the class members and are based on the same legal theory.” *Flonase*, 284 F.R.D. at 217-18; *see also In re Janney Montgomery Scott LLC Fin. Consultant Litig.*, No. 06-cv-3202, 2009 WL 2137224, at *4 (E.D. Pa. July 16, 2009) (“When the named plaintiffs and putative class members seek to challenge the same allegedly unlawful conduct, the typicality requirement is usually satisfied even though different fact patterns may underlie the individual claims.”).

Here, Plaintiffs’ claims arise out of the same facts and legal theories that give rise to the claims of all class members: Reckitt implemented an anticompetitive plan to inflate brand Suboxone tablet prices and delay generic Suboxone tablets from entering the market. If the

¹⁸ Courts recognize that this requirement “can be met with surprising ease in most cases, because the majority of class action decisions support the view that when it is alleged that the same unlawful conduct was directed at or affected both the named plaintiff and the class sought to be represented, the typicality requirement is met.” *Dodge v. Cambrex Corp.*, No. 03-cv-4896, 2007 WL 608365, at *5 (D.N.J. Feb. 23, 2007) (citation omitted).

Court certifies the proposed issues class only as to the unlawful conduct issues, that will set the parameters for the EPP class litigation. Individual factual issues related to plaintiff-specific injury and damages from the anticompetitive conduct will not be decided by the class trial. Such issues will only become relevant in later, non-class litigation by individual purchasers to prove their own antitrust injuries and damages. Here, EPPs and the Class members assert claims based upon common legal theories and an identical course of conduct. Typicality is satisfied.

iv. Plaintiffs and Their Counsel Will Adequately Represent the Classes

Rule 23(a)(4) requires that the proposed class representatives will “fairly and adequately protect the interests of the class.” FED. R. CIV. P. 23(a)(4). The Court must measure the adequacy of representation by two standards: (1) “ensure that the named plaintiff and its counsel have the ability and the incentive to represent the claims of the class vigorously,” and (2) “that there is no conflict between the individual’s claims and those asserted on behalf of the class.” *In re Domestic Drywall Antitrust Litig.*, 322 F.R.D. 188, 199 (E.D. Pa. 2017).

The adequacy standard is met here. First, Plaintiffs are represented by experienced counsel thoroughly familiar with litigating complex class actions. Hilliard & Shadowen LLC, Wexler Wallace LLP, and Motley Rice LLC (“Interim Co-Lead Counsel”), and Spector Roseman & Kodroff PC (“Liaison Counsel”) have served in leadership roles in numerous consumer and antitrust class actions, including similar indirect purchaser pharmaceutical antitrust class actions involving delayed generic competition.¹⁹ Since the inception of this litigation, Interim Co-Lead Counsel and Liaison Counsel have consistently demonstrated the willingness and ability to fairly and adequately represent the proposed Class.

¹⁹ See Firm Resumes at Ex. 2 to Wexler Decl.

Second, there is no likelihood of a conflict of interest among class members. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (“The adequacy inquiry under Rule 23(a)(4) serves to uncover conflicts of interest between named parties and the class they seek to represent.”); *In re Bulk (Extruded) Graphite Prods. Antitrust Litig.*, No. 02-cv-6030, 2006 WL 891362, at *8 (D.N.J. Apr. 4, 2006) (“[A]rguments [against class certification based on potential conflicts] are unavailing except in the rarest of cases where a conflict is so palpable as to outweigh the substantial interest of every class member in proceeding with the litigation.”) (citation omitted). Here, Plaintiffs’ interests in establishing Defendant’s liability for anticompetitive conduct are fully aligned with those of the absent Class members.

C. The Third Circuit’s Implied Ascertainability Requirement Doesn’t Apply and is Satisfied in Any Event.

i. Ascertainability is not considered in connection with a Rule 23(b)(2) class.

There is no ascertainability requirement with respect to Plaintiffs’ Rule 23(b)(2) class. As the Third Circuit held in *Shelton v. Bledsoe*, 775 F.3d 554, 563 (3d Cir. 2015), “it would be illogical to require precise ascertainability in a suit that seeks no class damages. The general demarcations of the proposed class are clear . . . and that definition makes the class sufficiently ascertainable for the purpose of Rule 23(b)(2).” (quoting *Floyd v. City of New York*, 283 F.R.D. 153, 172 (S.D.N.Y. 2012)); *City Select Auto Sales, Inc. v. BMW Bank of N. Am., Inc.*, 867 F.3d 434, 439 n.2 (3d Cir. 2017) (Scirica, J.) (“The ascertainability standard is not applicable to Rule 23(b)(2) classes.”); *Wright v. City of Wilmington*, 677 Fed. Appx. 95, 97 (3d Cir. 2017).

Rule 23(b)(2) has a “cohesiveness” test instead; plaintiffs must show that the class’s claims are common ones and that injunctive relief will benefit the class as a whole. *Cave v. Saxon Mortg. Servs.*, Civ. Nos. 11-4586, 12-5366, 2016 U.S. Dist. LEXIS 141033, *32-33 (E.D. Pa. Oct. 11, 2016). “Rule 23(b)(2) applies only when a single injunction or declaratory judgment

would provide relief to each member of the class. It does not authorize class certification when each individual class member would be entitled to a different injunction or declaratory judgment against the defendant.” *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 360 (2011).

Here, Plaintiffs seek an injunction that would help remedy the ongoing anticompetitive effect of Reckitt’s misconduct, such as, for example, compulsory licensing of the film patents to generic competitors, a mandated reduction in Reckitt’s price of the branded film, and/or corrective disclosures concerning the pretextual safety concerns that Reckitt espoused regarding the Suboxone tablet. Thus, all declaratory and injunctive relief granted will target Reckitt’s market-wide conduct and affect all EPP market participants. The proposed 23(b)(2) class is cohesive.

ii. If ascertainability applies at all to the Rule 23(c)(4) issues class, the only concern is whether the class is appropriately defined.

The Third Circuit has not squarely addressed whether ascertainability must be analyzed in Rule 23(c)(4) issues classes. However where, as here, no damages class is sought, the reasoning of *Shelton* logically applies. So long as the “general demarcations of the proposed class are clear,” there is no additional ascertainability inquiry. *Shelton*, 775 F.3d at 563.²⁰

Two district courts in this Circuit have been faced with whether the Rule 23(b) ascertainability standard applied in the context of Rule 23(c)(4) issues class certification. Neither concluded that it did. In *Gonzalez v. Corning*, 317 F.R.D. 443, 503-28 (W.D. Pa. 2016) (Flowers Conti, C.J.), the court conducted an 86-page analysis of all elements of the proposed Rule 23(b)(3), (b)(2), and (c)(4) classes without at all addressing whether the *Byrd* or *Carrera*

²⁰ In *Byrd*, the Third Circuit acknowledged that the ascertainability inquiry “will not be relevant in every case.” 784 F.3d at 165. The court also clarified that neither “underinclusiveness” nor “overly broad” classes are a reason for denying class certification on ascertainability grounds. *Id.* at 166-69.

elements of ascertainability were satisfied in connection with the Rule 23(c)(4) issues class. The Third Circuit affirmed the decision. *hassine*, 885 F.3d 186, 202 (3d Cir. 2018).

Similarly, in *Cave*, the district court rejected an attack on the ascertainability of the “Cave I” issues class as misplaced and chose to analyze that class under the “cohesiveness” framework discussed above with respect to Rule 23(b)(2) injunctive classes. *Cave*, 2016 U.S. Dist. LEXIS 141033 at *4, n.1, 30-47. Unlike Rule 23(b)(3) ascertainability analysis, it did not evaluate whether there was an administratively feasible method for identifying class members.

Although neither *Gonzales* nor *Cave* applied ascertainability to Rule 23(c)(4) classes and the *Shelton* Court’s analysis of Rule 23(b)(2) is analogous, there *are* class notice requirements and opt out opportunities in Rule 23(c)(4) issues classes that are not present in the Rule 23(b)(2) context. This distinction suggests that if the ascertainability test applies to the Rule 23(c)(4) issues classes, only the first prong is relevant, *i.e.*, the class must be defined with reference to objective criteria to allow for adequate class notice. The presence of an “administratively feasible” method of identifying all class members is not implicated because there will be no trial on class-wide injury or aggregate damages. *Cf. In re Comcast Corp. Set-Top Cable TV Box Antitrust Litig.*, 656 Fed. Appx. 8, 9 (3d Cir. 2016) (reversing denial of settlement class certification on ascertainability grounds and holding that “the concern that ‘[t]he method of determining whether someone is in the class . . . be *administratively feasible*,’ is not implicated by this case, because the settlement agreement removes the need for trial.”) (Scirica, J.) (emphasis added) (internal citation omitted).

The class for which certification is sought under Rule 23(c)(4) fully comports with Rule 23(c)(1)(B). The class is marked by a “readily discernible, clear, and precise statement of the parameters defining the class.” *Wachtel v. Guardian Life Ins. Co. of Am.*, 453 F.3d 179, 187 (3d

Cir. 2005). The proposed class is “defined with reference to objective criteria.” *Byrd*, 784 F.3d at 163. It is defined to comprise (1) “persons or entities” (2) “who purchased and/or paid for some of all of the purchase price for [Suboxone] in any form” (3) “for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries” during the period of anticompetitive conduct. Each component of this definition is an “objective description of prospective class members.” *Bello v. Beam Global Spirits & Wine, Inc.*, No. 11-cv-5149, 2015 WL 3613723, at *11 (D.N.J. June 9, 2015).

Reputable notice and claims administration firms have devised notices that have been judicially approved and given to classes of end-payor plaintiffs defined similarly to the EPPs in this case numerous times, in this Circuit and throughout the country. Carla Peak from the notice and claims administration firm of KCC, LLC (“KCC”) has provided a Declaration listing some of the many cases in which notices of the type at issue here were proposed, judicially approved, and delivered to TPPs and consumers in pharmaceutical antitrust cases wherein a litigation class of EPPs was certified. Peak Decl. at ¶ 6. Such notice programs have served as the best notice practicable by fulfilling the requirements detailed in the Judges' Class Action Notice and Claims Process Checklist and Plain Language Guide endorsed and published by Federal Judicial Center. Those guidelines demand that, for notice to qualify as the best practicable, it must reach between 70% and 95% of the TPPs and consumers in the certified class. Peak Decl. at ¶ 7. Thus, while Plaintiffs do not believe that *any* ascertainability analysis is required in the Court’s consideration of certification of a Rule 23(c)(4) class that does not include damages, Plaintiffs have submitted evidence that the proposed issues class can be given notice.

Even if the Court proceeded with a full-blown ascertainability analysis of Plaintiffs’ proposed issues class, the requirement is satisfied by the evidence accompanying Plaintiffs’

motion here. The Declaration of Myron Winkelman demonstrates that records exist containing the identities of every TPP and consumer paying all or part of the purchase price for branded and generic Suboxone during the class period. Ex. 4 to Wexler Decl. at ¶¶ 18-38; Ex. 1 to Wexler Decl. (“Exemplar Class Member Identification Data”). Plaintiffs have submitted the Declaration of one of the Interim Co-Lead Counsel, Kenneth A. Wexler, who describes how Plaintiffs could obtain these records for the great majority of class members. Wexler Decl. at ¶¶ 11-15. Interim Co-lead Counsel could then utilize the services of OnPoint Analytics to process the information and generate a list of these TPPs and consumers. Wexler Decl. at ¶¶ 12-13; Ex. 6 to Wexler Decl. at ¶ 7. The few class members that might not be picked up in the available data maintain or have their own access to records of their purchases and they can self-identify with these records, either at a claims process or before, as ordered by the Court.²¹ EPPs can thus show that putative class members can be identified through a reliable and administratively feasible methods.

²¹ According to the Winkelman Declaration, the top 15 retail pharmacies account for approximately 71% of the prescriptions filled in the United States. Winkelman Decl. at ¶ 37. The addition of PBM and TPP records further serve as an additional source of class member identification. *See* Winkelman Decl. at ¶ 21 (top four PBMs alone account for 80% of the market); Ex. 1 to Wexler Decl. Nonetheless, some small number of uninsured, cash-paying consumers would not show up in TPP and PBM databases or the top 15 retail pharmacies and would have to self-identify with their personal or pharmacy records. However, given the length of the class period, many of these consumers were likely insured for at least some period of time, lessening the number of individuals not picked up through the proposed subpoena methodology. Fully uninsured consumers made up only 9-13% of the national population base from 2013-2016. *See* “Health Insurance Coverage of the Total Population” at <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>

D. The Proposed Class satisfies the Gates Test for Rule 23(c)(4) issues class certification

The proposed Class is appropriate for certification as a Rule 23(c)(4) “issue only” class on unlawful conduct under *Gates*. All factors support certification. *Gates*, 655 F.3d at 273.

(a) The type of claims and issues in question are susceptible to efficient class-wide resolution

The issues to be certified for class-wide resolution are focused on Reckitt’s conduct and are common to the entire Class: whether Defendant willfully maintained monopoly power in the relevant market; whether Defendant’s actions were anticompetitive; and whether there exist cognizable, non-pretextual, procompetitive justifications for Defendant’s actions. *See supra*, Section IV.B.ii.

(b) The overall complexity of the case warrants certification of an issues class

Proof of anticompetitive and deceptive conduct centers on common evidence tied to Reckitt’s actions, but that analysis requires extensive document review, deposition testimony, and expert analyses of complicated issues that should only be done once, for all interested parties. Similarly, proof of monopoly power depends on expensive and complex expert aggregate data analysis that should only be done once. The issues in this case are complex issues, but they are also common issues susceptible of being tried with common proof. This factor weighs in favor of certification.

(c) Partial certification offers efficiencies given realistic procedural alternatives

Certifying an issues class would also advance the claims of absent Class members in an efficient manner by allowing all class members to benefit from a single adjudication on the issue of unlawful conduct. There are no realistic procedural alternatives here given that the cost of

litigating the unlawful conduct issues outweighs any individual award. An individual consumer in the proposed Class may have damages of only \$500. That person will not rationally spend years litigating against Defendant or spend hundreds of thousands of dollars needed for expert testimony to prove all the elements of unlawful conduct *and* impact and damages. On the other hand, after a class-wide judgment is secured on the complex and expensive issues presented for certification here, it would be substantially easier and more feasible for that person to pursue their own injury and damages claim in their own jurisdiction, particularly where many of the state laws at issue here have fee-shifting provisions and the proof necessary for their damages and injury claim consists of their own purchase records. Lastly, in contrast to the application of collateral estoppel (which would be repeatedly contested by all the myriad parties in non-class satellite litigation), the certification of an issues class here allows for the final adjudication of common liability issues.

(d) The substantive law underlying the claims supports certification of an issues class

The substantive law here lends itself well to certification of an issues-only class. The elements of EPPs' monopolization claim ("Count I") are "(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 678 (E.D. Pa. 2014) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966)). The elements of EPPs' attempted monopolization claim ("Count II") are "(1) that the defendant has a specific intent to monopolize, and (2) that the defendant has engaged in anticompetitive conduct that, taken as a whole, creates (3) a dangerous

probability of achieving monopoly power.” *W. Penn Allegheny Health Sys. v. UPMC*, 627 F.3d 85, 107 (3d Cir. 2010).

Almost all of the state statutes invoked by EPPs mirror federal antitrust law and will be satisfied through satisfaction of the elements described above and in the issues class definitions.²² The Court held at the motion to dismiss stage that the Florida, Michigan, Minnesota, Nevada, New York, Pennsylvania, and Virginia consumer protection statutes require an additional showing of deception (*i.e.*, consumer protection statutes invoked in Count III). *Suboxone*, 64 F. Supp. 3d at 700-03. Deception, however, will be proven through the same evidence of misconduct that proves EPPs’ and the other plaintiffs’ antitrust claims, such as the sham Citizen Petition and fabricated safety concerns related to the Suboxone tablet. *Id.* EPPs’ proposed issues class includes both the “anticompetitive” element and the “deceptive” element for trial, thus mirroring this Court’s motion to dismiss rulings.

(e) Issues class certification is consistent with the constitutional and statutory rights of the class members and Defendant

There are no unique constitutional or statutory issues here and the constitutionality of class actions is well-established. A certification under Rule 23(c)(1)(4) will not present any Seventh Amendment problems, because the jury that will decide the class-wide unlawful conduct issues will not be interfering with any later jury that will decide any plaintiff-specific antitrust injuries and damages. The second-wave juries will take the class-wide jury’s finding about whether the Defendant violated the antitrust laws and will then decide whether the specific plaintiff in that follow-on case has suffered antitrust injury. If so, that second jury will calculate

²² See Appendix A.

the specific plaintiff's damages. That is, no second-wave jury will be re-examining any question that was already decided in the class-wide jury trial.

(f) The preclusive effect of resolving the merits for the Classes is a valuable efficiency

Plaintiffs' proposed issues-certification approach protects Plaintiffs' ability to secure redress by establishing some crucial and complex issues on a class-wide basis, while still allowing plaintiffs to secure injury and damages findings on an individual basis. And if Defendant wins, it will provide final repose.

(g) Certification of an issues class will help effective and fair resolution of the remaining issues

Resolution of the indisputably common issues will resolve the most complex and time-consuming aspects of the case, allowing individual plaintiffs to proceed with individual damage claims at a much lower cost. The "remaining issues"—antitrust injury and damages—could be proven by individual plaintiffs in follow-up litigation with evidence of, *inter alia*, purchase records showing the price the plaintiff paid for brand and generic Suboxone tablets and brand Suboxone film and a straightforward calculation of what the plaintiff would have paid in the but-for world determined by the first issues-class jury.

(h) The resolution of remaining issues in individual proceedings will not prejudice any individual's right to a remedy

Individual proceedings for plaintiff-specific antitrust injury and damages will not prejudice any individual because the monetary relief sought is not indivisible and resolution of one plaintiff's injury and damages claim will not practically determine the claims of others. Should one individual plaintiff lose on the merits in follow-up litigation on their specific injury and damages, it will not prejudice other individual plaintiffs.

(i) The evidence presented on the issues certified is common to the class

Trying the issue of unlawful conduct for the issues classes proposed here would result in fact-finding related to: (1) Defendant’s unlawful conduct (*e.g.* the reasons behind the scheme to discredit the Suboxone tablet, the merits of the Citizen’s Petition, and Reckitt’s subjective intent to monopolize); (2) causation (*i.e.*, the contours of the but-for world, including what number of generic competitors would have entered the market and when); (3) market power (*i.e.* how the aggregate market perceives the interchangeability with other drugs to treat opioid dependence), and (4) ostensible “procompetitive justifications” by Defendant. Evidence derived from Reckitt’s documents, deposition testimony, expert analysis, and third-party discovery is all common to the class, even as to the deception element. *See Suboxone*, 64 F. Supp. 3d at 700 (noting EPPs plan to prove “that Reckitt fabricated a safety issue regarding Suboxone tablets for the sheer purpose of impairing generic competition and eliciting monopoly proceeds from consumers. This false safety issue was then allegedly broadcast to the FDA, doctors, other industry participants, and the public in an effort to destroy demand for Suboxone tablets.”).

In contrast, an individual class member’s later trial of antitrust impact and damages issues would include fact-finding related to: (1) whether or not the individual plaintiff at issue made a purchase that would have been at a lower price and, if so; (2) the total number of overcharge purchases the plaintiff had and, (3) the difference between what the plaintiff paid and what the plaintiff should have paid in the aggregate. The primary evidence in such a follow up proceeding likely will be the plaintiff’s own purchase records.

Issues class certification also provides advantages to Defendant. If it is proven that there was no unlawful conduct, then all Class members will be bound by that decision, and Defendant can be assured that litigation is over.

V. CONCLUSION

For the foregoing reasons, End-Payor Plaintiffs respectfully request that the Court certify (1) a nationwide injunctive class under Rule 23(b)(2); and (2) a state statutory issues class under Rule 23(c)(4) of end-payors who purchased in California, Florida, Iowa, Michigan, Minnesota, Mississippi, Nevada, New York, Pennsylvania, Virginia, and Wisconsin on the issue of Reckitt's unlawful conduct, expressly enumerated above.

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Respectfully submitted,

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